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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/620,091	07/20/2000	Steven E. Cwirla	0300-0014	3774

7590

03/28/2002

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 03/28/2002

9

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/620,091

Applicant(s)

CWIRLA ET AL.

Examiner

Bradley L. Sisson

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-161 is/are pending in the application.
- 4a) Of the above claim(s) 1-84, 88 and 94-163 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 74, 85-87 and 89-93 is/are objected to.
- 8) ☐ Claim(s) 74, 85-87 and 89-93 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 July 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, SEQ ID NO: 208 in Paper No. 9 is acknowledged. The traversal is on the ground(s) that all of the proteins are functionally related as they are G-CSF modulators and are structurally related and are encompassed by one of seven generic sequences, no serious burden is placed upon the Office in searching the sequences. Argument is also presented where at page 2 of the Response of 14 January 2002 applicant directs attention to M.P.E.P. 803.04 and asserts that applicant should be entitled to have at least ten sequences examined. This is not found persuasive because even if the sequences do encode a multitude of G-CSF modulators, each is a separate chemical entity, having different amino acid composition. The aspect that applicant is entitled to an examination of ten sequences has not been found persuasive. While the restriction guidelines do suggest that such is possible, restriction requirements, especially where as here there is placed an undue burden on the Office in conducting a comprehensive search of private and commercial databases, restriction to a single sequence is proper.
2. The requirement is still deemed proper and is therefore made FINAL.
3. Claims 18-22, 37-41, 55-59, 69-73, 95-100, 119-123, 142-146, and 157-161 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.

Art Unit: 1634

4. In view of applicant's election of the sequence represented by SEQ ID NO:208, claims 1-16, 23-35, 42-53, 60-67, 75-84, 88, 100-117, 124-140, and 147-155 have also been withdrawn as they read on nonelected sequences.

Claim Objections

5. Claims 74, 85, 86, 87, and 89-93 are objected to because of the following informalities: The claims read on embodiments not elected by applicant. Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 74, 85-87, and 89-93 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. As presently claimed, the oligopeptide represented by SEQ ID NO:208 does not have to exhibit any activity or property. The specification does not enable the use of a polypeptide where it has no activity. Applicant is urged to consider amending the claims to where the recited peptide structure has a known activity that is enabled by the specification as originally filed.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 74, 85-87, and 89-93 rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility. As presently worded, the polypeptide of SEQ ID NO:208 does not have to exhibit any activity or property. Absent some specific, credible and useful property, the polypeptide represented by SEQ ID NO:208 and encompassed by the above-identified claims lacks utility.

Conclusion

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Thursday from 6:30 AM to 5 PM.
11. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Application/Control Number: 09/620,091

Page 5

Art Unit: 1634

12. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.



Bradley L. Sisson
Primary Examiner
Art Unit 1634

bls
March 22, 2002